



UNITED STATES PATENT AND TRADEMARK OFFICE

Dooley

JUN 7 2004

COMMISSIONER FOR PATENT  
UNITED STATES PATENT AND TRADEMARK OFFICE  
P.O. Box 1450  
ALEXANDRIA, VA 22313-1450  
www.uspto.gov

Office of Regulatory Policy  
HFD - 13  
5600 Fishers Lane  
Rockville, MD 20857

6131 04 JUL 17 21:04

Attention: Claudia Grillo

The attached application for patent term extension of U.S. Patent No. 5,610,163 was filed on March 15, 2004, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, Spiriva® HandiHaler® (tiotropium bromide inhalation powder), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)308-6916 (facsimile).

Karin Ferriter  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: Michael P. Morris  
Boehringer Ingelheim Corporation  
900 Ridgebury Road, P.O. Box 368  
Ridgefield, CT 06877-0368

je

2004E-0314

LET 1